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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MAHATAN, CHANNING

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 02/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/090,144

Applicant(s)

MARKOWITZ ET AL.

Examiner

Channing S Mahatan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

APPLICANTS' ARGUMENTS

Applicants' arguments, filed 03 December 2004, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-21.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claim 1 and all claims dependent therefrom have been amended to recite "A method of managing and retrieving biological data for efficient exploration and analysis..." which is considered vague and indefinite. It should be noted the instant claims recite "providing a data warehouse...", "providing a user interface...", and the steps of "receiving...", "correlating...", and "displaying...". Absent from the instant claims are any steps or acts of "managing" and/or "retrieving" biological data as indicated in the preamble. Therefore, the instant claims are vague

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and indefinite due to citing a preamble practice which is different from the actual method steps thus making it unclear whether the preamble or the method steps set forth in the claims after the preamble control the metes and bounds of the claims. Clarification of the metes and bounds, via clearer claim language, is requested.

Claims 1, 8, 15 and all claims dependent therefrom recite the limitations “first query” and “first sample set or gene set” which is confusing. The term “first” implies that there is at least a “second”, in this case, “query”/“sample set or gene set”. However, no “second” or additional “query”/“sample set or gene set” is indicated and therefore it is confusing what the intended term “first” is to impart to the instant claims in such absence. Clarification of the metes and bounds, via clearer claim language, is requested.

Claims 1, 8, 15, and all claims dependent therefrom recite the language “corresponding to” which is considered vague and indefinite. For instance, it is unclear the correspondence (or factors that define said “corresponding to” language) that the “sample data on bio-samples and donors” or the “DNA fragments” have to the “tissues and cell lines”. Clarification of the metes and bounds, via clearer claim language, is requested.

Claims 1, 15, and all claims dependent therefrom recite the language “responsive to” which is considered vague and indefinite. The language “responsive to” implies some form of criteria/responsiveness that “the correlated gene expression measurements” has with “the first query”, which is unclear. Applicants can resolve this issue by indicating what establishes/defines “responsiveness” (per se) “the correlated gene expression measurements” has with “the first query”. Clarification of the metes and bounds, via clearer claim language, is requested.

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Claims 4, 5, 11, 12, 18, 19, and all claims dependent therefrom recite the language “consistently expressed” & “consistently not expressed” which is considered vague and indefinite. Applicants’ have indicated in the ‘Response’ filed 03 December 2004 (page 13, lines 22-26) the following portion of the specification defines “consistently expressed” & “consistently not expressed”:

“In accordance with an embodiment of the present invention, Explorer 240 supports a variety of analysis methods and tools. For example, one of the basic gene expression analysis operations provided by the present invention is the Gene Signature tool. The Gene Signature tool identifies consistently present and absent genes from a gene set, G, over a sample set, S. The result of a Gene Signature on G and S consists of the pair {CPG (G, S), CAG (G, S)}, where CPG denotes consistently present genes and CAG denotes consistently absent genes. A threshold, such as $(card(S)-k)$, where $card(S)$ denotes the cardinality of set S and k is 1, 2, ..., n, is often used in computing Gene Signatures. A Gene Signature Differential analysis tool compares the results of two Gene Signature analyses and computes four new sets of fragments: those that are in both the first present gene set and the second absent gene set; those are in both the first absent gene set and second present gene set; those that are in both present gene sets; and those that are in both absent gene sets.” (page 12, beginning on line 4)

“For example, in a given gene set, G, and sample set, S, the sets of consistently present (“CPG”) and consistently absent (“CAG”) genes in S, maybe defined as follows:

$CPG(G, S) = \{g_i | \sigma(g_i, p, S) \geq card(S) - k \text{ and } g_i \in G\}$; $CAG(G, S) = \{g_i | \sigma(g_i, a, S) \geq card(S) - k \text{ and } g_i \in G\}$.” (page 24, beginning on line 20)

“In one embodiment of the present invention, the CPG, CAG, CPS, and CAP operations may be varied using an additional threshold, T, for defining the gene expression consistency in terms of the minimum number of samples out of the total number of samples in S, for which the genes are present or absent.” (page 25, line 17)

However, the cited portions fail to define “consistently expressed” and “consistently not expressed” in a clear and concise manner. Absent from the cited portions are particular values or criteria(s) to provide for the establishment of said “consistently” language. The above portion does recite the language of “consistently present genes” and “consistently absent genes” but not “consistently expressed” or “consistently not expressed”, wherein “CPG denotes consistently present genes” and “CAG denotes consistently absent genes”. Again, the term “consistently” implies some range of values or criteria(s) that establishes a level of consistency among DNA

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fragment expression data; thereby distinguishing it from DNA fragment expression that is not considered to be consistently expressed (refer to the 'Office Action' mailed 30 June 2004). If it is Applicants intent that a threshold (T) is to provide for "defining the gene expression consistency in terms of the minimum number of samples out of the total number of samples in 5, for which the genes are present or absent"; the instant claims are not representative of this and it becomes further unclear as to what is considered to be "minimum number of samples out of the total number of samples in 5" and the defining consistency of the level of expression for these minimum number of samples. Clarification of the metes and bounds, via clearer claim language, is requested.

LACK OF ANTECEDENT BASIS

Claims 4-7 recite the limitation "wherein the analysis comprises..." which lacks proper antecedent basis. Absent from claim 1 (which claims 4-7 are dependent from) is "the analysis" which claims 4-7 appear to provide further limitations. Clarification of the metes and bounds, via clearer claim language, is requested.

Claims Rejected Under 35 U.S.C. § 102

The rejection of claims 1, 4, 5, 8, 11, 12, 15, 18, and 19 under 35 U.S.C. § 102(b) as being anticipated by Bassett et al. (Gene expression informatics – it's all in your mine. Nature Genetics Supplement. January 1999. Volume 21, page 51-55) is maintained for reasons of record.

Applicants' argue in the 'Response' filed 03 December 2004 that Bassett et al. fails to teach the partitioning of a data warehouse into three separate databases, where each database is dedicated to a different type of data". However, this is not agreed with for the following reasons.

Bassett et al. reviews the technical and intellectual issues involved in the data processing, storing and retrieving, and analysis of gene expression information (page 51, left column, lines 37-41). An overview of the information system for large-scale genome expression experiments is depicted (Figure 1), such that physical array devices are connected/networked with data management warehouses (i.e. relational database) and interfaced with the web to provide image analysis, results & summaries, links to other databases, and accessibility to other applications (page 51, right column, lines 3-5; and page 52). Bassett et al. proposes for the construction of the data warehouse that essential information in the data warehouse can be represented into categories (i.e. separate databases within the data warehouse), wherein examples of the categories are listed: 1) hybridization targets/DNA (fragments) sequence and identifiers (claim 1 “fragment index”); 2) details of the cell types and/or tissue origin (claim 1 “clinical database”); 3) mRNA transcript quantitation/gene expression levels (claim 1 “gene expression database”); etc. (pages 53-54, beginning on the right column, line 10). The authors indicate integration of experimental data with external information resources (i.e. Entrez) thereby allowing a user to explore (claims 1, 8, & 15 step of “querying...”) the different resource nodes and to select the ‘most important records’ by user-defined or default criteria and then to summarize these results (claims 1, 8, 15 step of “correlating”) in a condensed overview of the findings relevant to genes that are up-regulated (present/present), down-regulated (absent/absent) or both (present/absent or absent present) (claims 4, 5, 11, 12, 18, & 19; page 54, beginning on the left column, line 56). Finally, Bassett et al. describe critical aspects of the visualization/display of the genome wide expression data and state current examples of graphical displays to provide snapshots or

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overviews said expression data (claims 1, 8, & 15 step of “displaying...”). Thus, Bassett et al. anticipates the instantly claimed invention.

Claims Rejected Under 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicants are advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1-5, 8-12, and 15-19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Bassett et al. as applied to claims 1, 4, 5, 8, 11, 12, 15, 18, and 19 above, and further in view of Gopalkrishnan et al. (Star/Snow-flake Schema Driven Object-Relational Data Warehouse Design and Query Processing Strategies. Lecture Notes in Computer Science. 1999, Volume 1676, pages 11-22).

Bassett et al. is herein applied from above (refer to 35 U.S.C. § 102 Rejection). Bassett et al. does indicate the utilization of relational databases within the data warehouse (Figure 1),

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however, Bassett et al. fails to specifically recite the data warehouse is constructed in a star relational schema or a snowflake relational schema.

Gopalkrishnan et al. describes the construction/representation of data warehouses in a star relational schema (claims 2, 9, & 16) or a snowflake relational schema (claims 3, 10, & 17) (page 15, lines 1-15; and Figures 2).

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the invention to practice Bassett et al. in view of Gopalkrishnan et al. to utilize either star relational schema or snowflake relational schema in the construction of the data warehouse of Bassett et al. since Gopalkrishnan et al. indicates the utilization of a star or snowflake relational schema are popular representations of relational systems (page 11, lines 1-4).

OBJECTION TO CLAIM

Claim 1 is objected to because of the language "receiving the query" where it appears "the query" is intended to refer to the "first query". Appropriate correction is requested.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either 571-273-8300.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are

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available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify Applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables Applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Examiner Initials:

CSM

Ardin H. Marschel 2/14/05
ARDIN H. MARSCHEL
PRIMARY EXAMINER

Date:

February 14, 2005